## JC06 Rec'd PCT/PTO 23 SEP 2005

Approved for use through 3/31/2007, OMB 0651-0021

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### TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371**

ATTORNEY'S DOCKET NUMBER 2124.0070000

ION NO. HPKHOWN, see 37-CFR 1.5)
To Be Assigned 5 INTERNATIONAL APPLICATION NO. PCT/HU2004/000026 23 March 2004 (23.03.2004) PRIORITY DATE CLAIMED 24 March 2003 (24. 03.2003) TITLE OF INVENTION Process for the Synthesis of Amorphous Atorvastatin Calcium APPLICANT(S) FOR DO/EO/US Laszlo CZÍBULA et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. X This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). X has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. 8.  $\overline{X}$ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 12 13. X A preliminary amendment. 14. X An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. X A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. L A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

# JC20 Rec'd PET/PTO 23 SEP 2005

PTO-1390 (Rev. 07-2005)
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20. Other items or information: 1. International Scarch Report; and 2. Authorization to Treat a Reply as Incorporating an Extension of Time Under 37 C.F.R. § 1.136(a)(3).  The following fess have been submitted  The following fess have been submitted  21.   Basic national fee (37 CFR 1.492(a))  If the written opinion prepared by ISAUS or the international preliminary examination report prepared by IPEAUS indicates all claims satisfy provisions of PCT Articla 33(1)-(4)	U.S. APPLICATION NO. ((rknown, see, 37 CFR. 45)				PCT/HU2004/000026		2124.0070000	
21.	1. Internation	nal Search Re	port; and	corporating an Extens	ion of Time Un	der 37 C.F.R. § 1.1:	36(a)(3).	
22. Examination fee (37 CFR 1.492(c))  17 the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	The foll	owing fees have b	een submitted	<del></del>		CALCULATIONS	PTO USE ONLY	
If the written opinion prepared by ISAUS or the international preliminary examination report prepared by IPEAUS indicates all claims satisfy provisions of PCT Article 33(1)-(4)	21. X Basi	21. X Basic national fee (37 CFR 1.492(a))				\$ 300.00		
SpiPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	22. X Exam	nination fee (37 CF	FR 1.492(c))					
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)	by IPEA/	US indicates all cl						
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  Total Sheets	If the written opin IPEA/US Search fee (37 C International Sea previously	nion of the ISA/US indicates all claim FR 1.445(a)(2)) his onal Searching Au arch Report prepar y communicated to						
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  Total Sheets		TOTAL OF 21 22	900.00					
thereof (round up to a whole number)   x \$250	sequence electronic	e for specification e listing in complia c medium) (37 CF	700,00					
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  CLAIMS NUMBER FILED NUMBER EXTRA RATE \$  Total claims 3 - 20 = 0	Total Sheets	Extra Sheets	ra Sheets Number of each additional 50 or fraction RATE					
after the date of commencement of the national stage (37 CFR 1.492(h)).  CLAIMS NUMBER FILED NUMBER EXTRA RATE  Total claims 3 - 20 = 0 x \$ 50 \$ 0  Independent claims 1 - 3 = 0 x \$ 200 \$ 0  MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$ 360 \$ \$ 0  MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$ 360 \$ \$ 0  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$ 900.00  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE = \$ 900.00  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$ 40.00 per property + \$ TOTAL FEES ENCLOSED = \$ 900.00  Amount to be refunded: \$ Amount to be	11 - 100 =	0 /50 =			x \$250	\$ 0		
Total claims 3 - 20 = 0 x \$ 50 \$ 0  Independent claims 1 - 3 = 0 x \$ 200 \$ 0  MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$ 360 \$  TOTAL OF ABOVE CALCULATIONS = 0  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$ 900.00  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +   TOTAL NATIONAL FEE = \$ 900.00  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +   TOTAL FEES ENCLOSED = \$ 900.00  Amount to be refunded: \$  Amount to be			\$					
Independent claims  1 - 3 = 0	CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$		
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 \$  TOTAL OF ABOVE CALCULATIONS = \$ 0  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$ 900.00  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE = \$ 900.00  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + TOTAL FEES ENCLOSED = \$ 900.00  Amount to be refunded: \$ Amount to be	Total claims		3 - 20 =	0	x \$ 50	\$ 0		
TOTAL OF ABOVE CALCULATIONS = \$ 0  Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$ 900.00  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE = \$ 900.00  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  TOTAL FEES ENCLOSED = \$ 900.00  Amount to be refunded:  Amount to be	Independent claims 1 - 3 =		0	× \$200				
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  SUBTOTAL = \$900.00  Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  TOTAL NATIONAL FEE = \$900.00  Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  TOTAL FEES ENCLOSED = \$900.00  Amount to be refunded:  Amount to be	MULTIPLE DEP	ENDENT CLAIM(S						
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PTO-1390 (Rev. 07-2005)
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а. 🔲	A check in the amount of \$								
ь. 🗆	Please charge my Deposit Acc A duplicate copy of this sheet	count Nois enclosed.	in the amount of \$	to cover the above	fees.				
c. X	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-0036</u> . A duplicate copy of this sheet is enclosed.								
d. X	Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.								
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.									
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SEND A	LL CORRESPONDENCE TO:		<i>~</i>	SIGNATURE A	Caus				
CUS	STOMER NUMBER	26111		Heidi L.	Kraus				
				NAME 43,7	730				
				REGISTRATION NUMBER					

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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Czibula et al.

Appl. No.: To Be Assigned

(U.S. Nat'l Phase of PCT/HU2004/000026)

Int'l Filing Date: 23 March 2004 (23.03.2004)

For: Process for the Synthesis of Amorphous

Atorvastatin Calcium

Confirmation No.: To Be Assigned

Art Unit: To Be Assigned

Examiner: To Be Assigned

Atty. Docket: 2124.0070000

Authorization to Treat a Reply as Incorporating an Extension of Time Under 37 C.F.R. § 1.136(a)(3)

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

The U.S. Patent and Trademark Office is hereby authorized to treat any concurrent or future reply that requires a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. The U.S. Patent and Trademark Office is hereby authorized to charge all required extension of time fees to our Deposit Account No. 19-0036, if such fees are not otherwise provided for in such reply.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Heidi L. Kraus

Attorney for Applicants Registration No. 43,730

Date:

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